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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,106	11/25/2003	Nasr-Eddine Djennati	ISA-003.01	4845
25181	7590	10/18/2005	EXAMINER WEST, PAUL M	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			ART UNIT 2856	PAPER NUMBER

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/722,106	DJENNATI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul M. West	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06022005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 15 is objected to because of the following informalities: The word "fields" appears to be incorrect and should most likely be changed to --field--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 3,5,9,13, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. As to claims 3,5,9, and 13, the word "may" or the phrase "may be" which appears in each claim is indefinite. It is unclear whether the words which follow "may" or "may be" are meant to limit the claim.
5. As to claim 21, "said magnets" lacks antecedent basis in the claim and renders the claims indefinite. Further, it is unclear how two electromagnets can be activated alternately and still produce a magnetic field which is constant. What is the magnetic field constant with respect to, and over what period of time is it constant?

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7, 9, 10, 13, 18, 19, 22-27, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goddard (EP 0400847 A2).

8. As to claims 1, 5-7, 9, 10, and 22, Goddard teaches a device for determining the coagulation state of a sample comprising: a volume 23 which serves as a filling chamber for receiving a sample of blood to be analyzed; a filling device 22 for filling the chamber 23; a spherical particle 29 disposed within the volume wherein the particle 29 is made of steel, which is ferromagnetic and experiences a force when placed in a magnetic field; a means 30 for applying a magnetic field to a part of the volume 23; and a Hall Effect sensor operative to detect movement or position of the particle (Col. 3, lines 3-6); wherein the movement or position of the particle is correlated to the coagulation state of the sample.

9. As to claims 2-4, Goddard teaches the device having a display 2 which displays a clotting time, a value which may be correlated with a disturbance in hemostasis (Col. 6, lines 57-58; Col. 7, lines 1-3).

10. As to claims 13, Goddard teaches the particle comprising steel with a thromboplastin reagent coating (Col. 3, lines 52-55).

11. As to claims 18 and 19, Goddard teaches the interior walls of the chamber being coated with thromboplastin (Col. 3, lines 49-55).

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12. As to claim 23, Goddard teaches the device comprising circuitry for measuring the time elapsed from introduction of a sample until a coagulation state is reached (Col. 3, lines 22-34).

13. As to claim 24, Goddard teaches a control means 33.

14. As to claim 25, Goddard teaches a device for determining the coagulation time of a sample, the device comprising: a container defining a chamber 23 for holding a quantity of the sample, wherein the chamber holds a particle 29; a magnetic device 30 co-operating with the container 23; and a magnetic field which causes the particle 29 to migrate to and fro within the chamber 23 through the sample.

15. As to claims 26 and 27, Goddard teaches the chamber having a volume of less than 20 $\mu$ L which includes volumes less than 5 $\mu$ L (Col. 2, lines 25-26).

16. As to claim 28, Goddard teaches the device comprising a means 3 for heating the chamber.

17. As to claim 29, Goddard teaches the chamber being formed in a disposable support strip 21 which is removable from the device (Col. 5, lines 42-43).

18. As to claim 30, Goddard teaches a method for determining the coagulation state of a sample comprising: providing a sample containing a particle 29 comprising a material (steel) which experiences a force when placed in a magnetic field; applying a magnetic field to the sample by means of electromagnet 30; and using a magnetic field sensor to detect the movement or position of the particle 29 (Col. 3, lines 3-6) to determine the coagulation state of the sample.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 11, 12, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard (EP 0400847 A2).

21. As to claims 11 and 12, Goddard does not teach the particle having a size between 2 and 500 $\mu$ m or between 2 and 20 $\mu$ m, however Goddard does teach the particle being of a specific size base on the size of the sample and of the chamber being used. It would have been obvious to one of ordinary skill in the art to change the size of the particle based on the size of the other equipment being used and the spacing of the magnet from the chamber, and further it has been held that a change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

22. As to claims 15-17, Goddard does not teach using a specific strength of magnetic field, however it would have been obvious to one of ordinary skill in the art to use a magnetic field strength between 10 and 20 mT or any reasonable magnetic field strength that is capable of moving the particle before coagulation but causes substantially less movement after coagulation because this is the only way the device can work.

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23. Claims 8, 14, 20, 21, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard in view of Oberhardt et al. (5350676).

24. As to claim 8, Goddard teaches all of the limitations as set forth above but does not teach the filling device comprising a capillary. Oberhardt et al. teach a coagulation measuring device with a filling chamber 14 and filling device which comprises a capillary 26 (Col. 8, lines 41-43). It would have been obvious to one of ordinary skill in the art to use a capillary as taught by Oberhardt with the device of Goddard because it would allow a sample to be pulled into the filling chamber while preventing the sample from easily spilling out of the chamber.

25. As to claim 14, Goddard does not teach having more than one particle disposed in the volume. Oberhardt et al. teach a coagulation measuring device which moves multiple particles (Col. 6, lines 1-3) back in forth in a sample using a changing magnetic field. It would have been obvious to one of ordinary skill in the art to use multiple particles as taught by Oberhardt with the device of Goddard because multiple particles would reduce statistical error by providing data at multiple spatial points within the sample.

26. As to claims 20 and 21, Goddard does not teach using two spaced apart electromagnets being alternately activated, but rather teaches one electromagnet which is alternately turned on and off. Oberhardt et al. teach using two magnets 400, 196 spaced apart one of which is an electromagnet 196 which alternately turns on and off. It would have been obvious to one of ordinary skill in the art to use two spaced apart magnets as taught by Oberhardt with the device of Goddard because two magnets

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would provide more control over the movement of the particle in opposite directions. It would have been further obvious to use two electromagnets because an electromagnet has more versatility than a permanent magnet, as it's intensity can be varied and it can be switched on and off.

27. As to claim 31, Goddard teaches a method of determining the coagulation time of a sample comprising: causing a particle 29 comprised of material (steel) which experiences a force when placed in a magnetic field to move through the sample; and noting as the coagulation time, an instant at which changes in the properties of the sample reduce the movement (Col. 3, lines 20-28). Goddard does not teach using multiple particles. Oberhardt et al. teach a coagulation measuring device which moves multiple particles (Col. 6, lines 1-3) back in forth in a sample using a changing magnetic field. It would have been obvious to one of ordinary skill in the art to use multiple particles as taught by Oberhardt with the device of Goddard because multiple particles would reduce statistical error by providing data at multiple spatial points within the sample.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul M. West whose telephone number is (571) 272-8590. The examiner can normally be reached on Monday-Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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